K081903

AUG 26 2008

510(k) Summary
for
Sirona Dental Systems
XIOS^{Plus} Wall-Module

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: August 7, 2008

2. DEVICE NAME

Proprietary Name:	XIOS^{Plus} Wall-Module
Common/Usual Name:	System, X-Ray, Extraoral, Digital
Classification Name:	Extraoral source x-ray system

3. PREDICATE DEVICE

Sirona Dental Systems Wall-Box K013659 (included in SIDEXIS) and Schick Computed Oral Radiology System K072134.

4. INTENDED USE

The XIOS^{Plus} Wall-Module and the XIOS^{Plus} Sensors are intended for acquisition of digital dental intraoral X-ray exposures.

5. DEVICE DESCRIPTION

The Sirona XIOS^{Plus} Wall-Module is an acquisition device for digital dental intraoral X-ray exposures. It comprises of the XIOS^{Plus} Wall-Module, one or two pluggable solid X-ray sensors and a SIDEXIS Software Plug-in, managing XIOS^{Plus} Wall-Module and Ethernet related tasks, and interfacing SIDEXIS. The XIOS^{Plus} Wall-

Module is connected via Ethernet to one or more PCs on which the Plug-in and SIDEXIS are running. Operation related information is displayed or signaled through a display or LEDs.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The overall design of the Sirona XIOS^{Plus} Wall-Module is similar to the Sirona Wall Box and Schick Intraoral Sensor Imaging System covered in the premarket notification K013659 and K072134 respectively. All devices are for intraoral exposures. All the sensors have similar image areas. The pixel size of the XIOS^{Plus} sensors is identical compared to Schick Intraoral Sensor Imaging System sensors, and smaller compared to the Sirona Wall-Box sensors. The acquired image matrix is higher compared to the Sirona Wall-Box sensors allowing a higher resolution of X-ray exposures and identical to the Schick Intraoral sensors. Sirona XIOS^{Plus} Wall-Module and Wall-Box communicate via Ethernet connection with SIDEXIS running on a PC whereas Schick Intraoral Sensor Imaging System communicates via USB-connection. All devices signal their readiness for an exposure. The XIOS^{Plus} Wall-Module device accommodates the connection of two sensors concurrently.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2008

Sirona Dental Systems GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K081903
Trade/Device Name: XIOS^{Plus} Wall-Module
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 8, 2008
Received: August 11, 2008

Dear Mr. Preiss:

This letter corrects our substantially equivalent letter of August 26, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known):

Device Name: XIOS^{Plus} Wall-Module

Indications for Use:

Unit for acquisition of digital dental intraoral X-ray exposures.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081903